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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,586	08/23/2007	Raymond Weinstein	GMU-0001	7191

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
04/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/566,586	WEINSTEIN ET AL.	
	Examiner	Art Unit	
	JEFFREY PARKIN	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-13,24,42 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-13 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/31/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Acknowledgment is hereby made of receipt and entry of the communication filed 16 March, 2011. Claims 1, 6-13, 24, 42, and 43 are pending in the instant application. Applicants' election of Group I (claims 1, 6-13, and 24) with traverse is noted. It was argued that the groups share a special technical feature. Applicants also noted that a lack of unity finding was not made in the international application. As previously set forth, groups I and II do not share a special technical because they are directed toward different scientific objectives that employ different protocols and reagents. Separate searches will clearly be required for each group. Concerning the international search report applicants are reminded that this report reflects the International Preliminary Examining Authority's (IPEA) non-binding opinion regarding lack of unity, novelty, inventive step, and industrial applicability. The examiner may adopt any portion or all of the report on patentability of the IPEA or ISA upon consideration in the national stage so long as it is consistent with U.S. practice. See M.P.E.P. § 1893.03(e). Accordingly the requirement is still deemed proper and is therefore made **FINAL**. Claims 42 and 43 stand withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Claims 1, 6-13, and 24 are currently under examination.

37 C.F.R. § 1.98

The information disclosure statement filed 31 January, 2006, has been placed in the application file and the information

referred to therein has been considered. Applicants are reminded that the listing of references in the specification is not a proper information disclosure statement (e.g., see pages 26-28 and 46-53). 37 C.F.R. § 1.98(b) requires a list of all patents, publications, applications, or other information submitted for consideration by the Office, and M.P.E.P. § 609.04(a), subsection I. states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

37 C.F.R. § 1.84

Acknowledgement is hereby made of receipt and entry of the drawings filed on 31 January, 2006, which are deemed to be acceptable.

35 U.S.C. § 120 Benefit

Acknowledgement is hereby made of applicants priority claim to PCT/US04/02064, filed 28 January, 2004. The first paragraph of the specification should be updated to reflect the priority claim.

Specification

The specification is objected to because of the following informalities: pages 20-53 are generally illegible and fail to conform to the preferred layout. See M.P.E.P. § 608.01. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use. Arrangement of the Specification As provided in 37 C.F.R. § 1.77(b), the

specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.

(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.

(f) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 C.F.R. § 1.97 and § 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING. (See M.P.E..P § 2424 and 37 C.F.R. § 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 C.F.R. § 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc.). Appropriate correction is required.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1, 6-13, and 24 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed toward a method of preventing HIV infection in a subject in need thereof, comprising: administering an effective amount of a vaccinia virus, wherein said amount is effective to prevent HIV infection, with the proviso that HIV nucleic acid is not contained within the vaccinia virus genome (claim 1) or a method of treating HIV infection in a subject in need thereof, comprising: administering multiple doses, each having an effective amount of an attenuated vaccinia virus to a subject infected with HIV, wherein said amount is effective to treat HIV infection and wherein each dose is administered at a predetermined time interval from the previous dose, and are effective to maintain protection against HIV infection (claim 24).

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

1) The disclosure fails to provide sufficient guidance pertaining to the mechanism of inhibition. It was noted by the inventors that changes in chemokine levels (e.g., MIP-1α, MIP-1β, or RANTES) did not appear to correllate with reduced replication. In order to practice the claimed invention the skilled artisan would need a rational understanding of which vaccinia virus gene product(s) are responsible for the modest impairment in viral replication, particularly if administering an attenuated virus or a different strain of vaccinia.

2) The disclosure fails to provide any suitable working embodiments. While it was noted that there was a reduction in viral replication from a single CCR5-tropic isolate in the study relied upon, it should also be emphasized that CCR5-tropic viruses were able to replicate, albeit with less efficiency as compared to the vaccinated group. Vaccination with vaccinia had

no effect on CXCR4-tropic viruses. The skilled artisan would also readily appreciate that simple *in vitro* culture assays are not reasonably predictive of clinical efficacy. The claims are clearly directed toward methods of treating or preventing HIV infection in a subject.

3) The state-of-the-art as it applies to HIV vaccines and therapeutics is best characterized as unpredictable (Stevenson, 2003; Gallo, 2005; McMichael, 2006; Connick *et al.*, 2007). To date there are no effective vaccines available for the prevention and treatment of HIV infection. Numerous attempts have been unsuccessful because of several factors: 1) The virus exists as a quasispecies which leads to immune evasion and rapid immune escape. 2) The correlates of protective/therapeutic immunity remain to be elucidated. Thus it is not readily manifest which immunogens, vectors, formulations, adjuvants, and immunization regimens will provide the desired outcome. 3) Since HIV frequently enters through mucosal compartments, it is imperative that a strong mucosal immune response be present to combat infection. 4) HIV has evolved elaborate mechanisms to evade the immune response (e.g., down-regulation of MHC class I molecules). 5) The immunopathogenesis of HIV infection is exceedingly complex and leads to a number of immune deficits that cannot be readily corrected. Large quantities of virus are produced on a daily basis. 6) There are no acceptable animal models that enable the skilled artisan to make direct extrapolations to the clinic. 7) HIV becomes integrated into the host genome thereby making its eradication virtually impossible. 8) HIV resides in various immunoprivileged compartments that make treating it that more difficult. The disclosure fails to address any of these caveats or provide any data that would lead

the skilled artisan to conclude that vaccinia virus vaccination would actually be effective at preventing or treating HIV infection.

Accordingly, when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Zachariah Lucas, can be reached at (571) 272-0905. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may

be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin/
Primary Examiner, Art Unit 1648

26 March, 2011